MCANDREWS, HELD & MALLOY, LTD. 500 West Madison Street, 34th Floor Chicago, Illinois 60661 2 Tel: (312) 775-8000; Fax: (312) 775-8100 Edward A. Mas II (pro hac vice application to be filed) 3 Filed emas@mcandrews-ip.com David D. Headrick (pro hac vice application to be filed) 4 dheadrick@mcandrews-ip.com Scott P. McBride (pro hac vite application to be filed) 5 smcbride@mcandrews-ip.com Kevin A. O'Connor (*pro hac vice* application to be filed) RICHARD W. WIEKING CLERK, U.S. DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA 6 koconnor@mcandrews-ip.com 7 SAN JOSE FINNEGAN, HENDERSON, FARABO 8 GARRETT & DUNNER, LLP 3300 Hillview Ave. 9 Palo Alto, CA 94307-1203 Tel: (650) 849-6600; Fax: (650) 849-6666 10 Robert F. McCauley III (Bar No. 162056) robert.mccauley@finnegan.com 11 12 Attorneys for Plaintiffs Abbott Laboratories and Abbott Cardiovascular Systems, Inc. 13 14 UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA 15 16 CO8 04962 PV 17 ABBOTT LABORATORIES and ABBOTT CARDIOVASCULAR 18 SYSTEMS, INC., COMPLAINT 19 Plaintiffs, 20 v. 21 MEDTRONIC, INC. and MEDTRONIC 22 VASCULAR, INC. 23 Defendants. 24 25 26 27

ORIGINAL

DEMAND FOR JURY TRIAL

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COMPLAINT

Plaintiffs Abbott Laboratories and Abbott Cardiovascular Systems Inc. ("Abbott"), for their Complaint against Defendants Medtronic, Inc. and Medtronic Vascular, Inc. (collectively, "Medtronic") allege as follows:

INTRADISTRICT ASSIGNMENT

1. This patent action is an excepted category for Civil L.R. 3-2(c), Assignment of a Division, and will be assigned on a district-wide basis.

RELATED CASE

- 2. Plaintiff Abbott Cardiovascular Systems, Inc.'s predecessor previously sued

 Defendant Medtronic, Inc. for infringement of the patent that is the subject of this action in <u>Advanced</u>

 <u>Cardiovascular Systems, Inc. v. Medtronic, Inc.</u>, Case No. 95-03577 DLJ, filed on October 10, 1995.
- 3. Medtronic, Inc. was found to have willfully infringed the patent that is the subject of this action, and was permanently enjoined from infringing the patent that is the subject of this action until October 29, 2008. The term of the patent that is the subject of this action extends, however, beyond October 29, 2008.
- 4. Pursuant to Civil L.R. 3-12, an administrative motion will promptly be filed in the 95-03577 action, asking the Court to consider whether the action that is the subject of this Complaint should be treated as a related case to the 95-03577 action.

THE PARTIES

- 5. Plaintiff Abbott Laboratories ("Abbott") is an Illinois Corporation with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.
- 6. Plaintiff Abbott Cardiovascular Systems Inc. is a California corporation with a principal place of business at 3200 Lakeside Drive, Santa Clara, California.
 - 7. Abbott Cardiovascular Systems Inc. is a subsidiary of Abbott Laboratories.
- 8. On information and belief, Medtronic, Inc. is a Minnesota corporation with its principal place of business in Minneapolis, Minnesota.

- 9. On information and belief, Medtronic, Inc. is engaged in the marketing, distribution, and/or selling of interventional medical devices, including balloon dilatation catheters, coronary stent systems, and drug-eluting stent systems in the United States.
- 10. On information and belief, Medtronic Vascular, Inc. is a Delaware corporation with its principal place of business in Santa Rosa, California.
 - 11. On information and belief, Medtronic Vascular, Inc. is a subsidiary of Medtronic, Inc.
- 12. On information and belief, Medtronic, Inc. and Medtronic Vascular, Inc. are engaged in the marketing, distribution, and/or selling of interventional medical devices, including balloon dilatation catheters, coronary stent systems, and drug-eluting stent systems in the United States.

JURISDICTION AND VENUE

- 13. This is an action for patent infringement and for declaratory judgment in a case of actual and justiciable controversy between Abbott Laboratories and Abbott Cardiovascular Systems Inc. (collectively "Abbott" or "plaintiffs"), on the one hand, and Medtronic, Inc. and Medtronic Vascular, Inc. (collectively "Medtronic" or "defendants"), on the other, arising under the declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, the United States Patent Laws, 35 U.S.C. § 101 et seq., and the All Writs Act, 28 U.S.C. §1651(a).
 - 14. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 15. Personal jurisdiction exists over defendant Medtronic Vascular, Inc., which is a corporation with its principal place of business within this judicial district.
- 16. Personal jurisdiction exists over defendants because they have continuous systematic, and substantial contacts with the State of California, including with respect to the marketing, distribution, and selling interventional medical devices, including balloon dilatation catheters, coronary stent systems, and drug-eluting stent systems in the State of California, and within this judicial district. In addition, this lawsuit arises from the defendants' imminent patent infringement activities believed to be directed towards the State of California, and within this judicial district.
- 17. Abbott is informed and believes, and on that basis alleges, that Medtronic routinely sells interventional medical devices, including balloon dilatation catheters, coronary stent systems, and drug-eluting stent systems in California and within this judicial district.

- 18. Abbott is informed and believes, and on that basis alleges, that over the last several years Medtronic has generated significant revenues from the sales of its products in California.
 - 19. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b)-(c).

COUNT I

DECLARATORY JUDGMENT OF INFRINGEMENT OF THE 233 PATENT AGAINST MEDTRONIC, INC. AND MEDTRONIC VASCULAR, INC. BY THE ENDEAVOR RX AND DRIVER RX PRODUCTS

- 20. Abbott incorporates by reference the allegations set forth in paragraphs 1-19 above as though fully set forth herein.
- 21. Abbott markets and sells medical devices used in the United States to treat coronary artery disease, including coronary angioplasty catheters, coronary stent systems, and drug-eluting stent systems. Medical devices such as these are used by physicians to perform percutaneous transluminal coronary angioplasty ("PTCA"), a minimally invasive procedure.
- 22. Abbott is informed and believes, and on that basis alleges, that Medtronic has made substantial and meaningful preparations to manufacture, use, import, offer to sell, and/or sell the Endeavor® Zotarolimus-Eluting Coronary Stent on the Rapid Exchange Stent Delivery System ("Endeavor RX") and DriverTM Rapid Exchange Coronary Stent System ("Driver RX") in the United States, including in the State of California and within this judicial district.
- 23. Abbott is informed and believes, and on that basis alleges, that Medtronic Vascular filed Premarket Approval Application ("PMA") No. P030009 for the Driver RX on or about April 10, 2003. The design of, and product specifications for, the Driver RX were substantially fixed by that date.
- 24. Abbott is informed and believes, and on that basis alleges, that the Driver RX was approved for commercial marketing on or about October 1, 2003.
- 25. Abbott is informed and believes, and on that basis alleges, that Medtronic Vascular filed PMA No. P060033 for the Endeavor RX on or about November 26, 2006. The design of, and product specifications for, the Endeavor RX were substantially fixed by that date.

- 26. Abbott is informed and believes, and on that basis alleges, that the Endeavor RX was approved for commercial marketing on or about February 1, 2008.
- 27. Abbott is informed and believes, and on that basis alleges, that the design and indicated use(s) of, and product specifications for, the Endeavor RX and Driver RX products remain substantially fixed and cannot be changed without further approval from the United States Food and Drug Administration ("FDA").
- 28. Abbott is informed and believes, and on that basis alleges, that on or shortly after October 30, 2008, Medtronic intends to market, distribute, and sell the Driver RX.
- 29. Abbott is informed and believes, and on that basis alleges, that on or shortly after October 30, 2008, Medtronic intends to market, distribute, and sell the Endeavor RX.
- 30. On or about August 15, 2008, Medtronic, Inc. moved to dissolve a permanent injunction prohibiting its infringement of U.S. Patent No. 5,451,233 ("the 233 patent"), as of October 29, 2008.
- 31. In its motion, Medtronic, Inc. stated that "Medtronic intends to market commercially and sell [the Endeavor RX and Driver RX] after . . . October 29, 2008."
- 32. Abbott is informed and believes, and on that basis alleges, that Medtronic has repeatedly confirmed that it will act on its stated intent to market commercially the Endeavor RX and Driver RX immediately after October 29, 2008.
- 33. Abbott Cardiovascular Systems Inc. is the exclusive United States licensee of the 233 patent, with the right to bring suit for infringement of the patent.
- 34. The 233 patent generally relates to a type of dilatation catheter called "rapid exchange."
- 35. The Endeavor RX and Driver RX products that Medtronic intends to make, use, import, offer to sell, and/or sell use rapid exchange technology.
- 36. Abbott is informed and believes, and on that basis alleges, that Medtronic's commercial manufacture, use, offers for sale, sales, and/or importation of its Endeavor RX and Driver RX products would infringe one or more claims of the 233 patent, including at least claim 3, under 35 U.S.C. § 271.

- 37. Abbott is informed and believes, and on that basis alleges, that Medtronic's infringement would be willful and with full knowledge of the 233 patent.
- 38. Abbott is under a reasonable apprehension that Medtronic's infringement of the 233 patent is imminent.
- Thus, an actual and justiciable controversy exists between Abbott and Medtronic regarding whether Medtronic's manufacture, use, importation, offers for sale, and/or sales of its Endeavor RX and Driver RX products would infringe the claims of the 233 patent, including at least claim 3 thereof, and whether such infringement would be willful and with full knowledge of the 233 patent.
- 40. To avoid legal uncertainty and the threat of the infringing Endeavor RX and Driver RX products, Abbott seeks a declaratory judgment that such manufacture, use, importation, offers for sale, and/or sales, and the acts of Medtronic alleged above relating thereto, would infringe the 233 patent, and that such infringement would be willful and with full knowledge of the 233 patent.
- 41. Medtronic's conduct as alleged above will result in irreparable harm to Abbott that cannot be compensated by monetary damages.

PRAYER FOR RELIEF

WHEREFORE, Abbott respectfully requests the Court to enter judgment in favor of Abbott and against Medtronic to include:

- A. A declaration that Medtronic, Inc.'s and Medtronic Vascular, Inc.'s manufacture, use, importation, offer for sale, and/or sale of the Endeavor® Zotarolimus-Eluting Coronary Stent on the Rapid Exchange Stent Delivery System ("Endeavor RX") and Driver™ Rapid Exchange Coronary Stent System ("Driver RX") products would infringe the claims of U.S. Patent No. 5,451,233, including at least claim 3 thereof.
- B. A declaration that such infringement would be willful and with full knowledge of the 233 patent.
- C. A permanent injunction preventing Medtronic, Inc. and Medtronic Vascular, Inc., and any affiliated entities, and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from:

- 1. manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the Endeavor RX and Driver RX products, and any colorable variation thereof that infringes claim 3 of the 233 patent, until the expiration of the 233 patent; and
- 2. any other activity with respect to the Endeavor RX and Driver RX products, and any colorable variation thereof that would constitute infringement of claim 3 of the 233 patent, until the expiration of the 233 patent.
 - D. Damages for infringement, with interest and trebled, pursuant to 35 U.S.C. § 284.
 - E. Costs and expenses in this action.
- F. A declaration that this is an exceptional case, and an award to Abbott of its costs and attorneys' fees, disbursements, and costs pursuant to 35 U.S.C. § 285 or other applicable law, in connection with this action.
 - G. Any such further relief as this Court may deem just and proper.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP

Dated: October 29, 2008

Robert F. McCauley III (Bar No. 162056)

Attorneys for Plaintiffs Abbott Laboratories

Abbott Cardiovascular Systems Inc.

DEMAND FOR JURY TRIAL

Plaintiffs respectfully demand a jury trial on all issues so triable.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP

Dated: October 29, 2008

Robert F. McCauley III (Bar No. 162056) Attorneys for Plaintiffs

Abbott Laboratories

Abbott Cardiovascular Systems Inc.